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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/920,365 | 08/03/2001 | Michel Andre Crepeau | VIT-2 (5500*86) | 6748 |

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[REDACTED] EXAMINER

OH, SIMON J

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1615

DATE MAILED: 01/14/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/920,365 | Applicant(s) CREPEAU, MICHEL ANDRE |
| | Examiner Simon J. Oh | Art Unit 1615 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Acknowledgment of receipt is made of the applicant's declaration, along with all appropriate fees. The above was received on October 19, 2001, for Application No. 09/920,365.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kardys (U.S. Pat. No. 3,932,634) in view of Perricone *et al.* (U.S. Pat. No. 6,162,419) and Josse (U.S. Pat. No. 4,075,333).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Kardys teaches a high potency vitamin formulation which easily disperses in water. This formulation includes at least one oil-soluble vitamin selected vitamin A, vitamin D₂, vitamin D₃, vitamin E, or combinations thereof (See Column 2, Lines 15-53). Another principal component is an emulsifier or dispersing agent, described as a polyoxyethylene derivative of certain high

Art Unit: 1615

molecular weight fatty acid esters, with the sorbitan fatty acid esters cited as a specific example (See Column 1, Lines 20-41 and Column 2, Lines 53-68). The third principal component of this formulation is chosen from the group comprising polyethylene glycol 400 monooleate, decaglycerol dioleate, or decaglycerol trioleate (See Column 3, Lines 1-12). Both the second and third principal components of this composition fall under the category of what the applicant describes as non-ionic surfactants. In addition, Kardys teaches that the oil soluble vitamins may also be blended with corn oil or other mineral or vegetable oil (See Column 3, Lines 22-48; and Examples II, III, IV, and X). Example X in Kardys also shows a formulation that includes ethanol or alternatively, normal propanol, in its formulation (See Column 8, Lines 19-32), both of which fall under the description of the C₂ to C₆ mono-hydroxy alcohol described in Claim 1. Kardys also teaches that this formulation can disperse rapidly in water, usually in less than a minute, within a matter of seconds, to give clear and stable vitamin solutions of high potency (See Column 2, Lines 3-13; Column 3, Lines 13-38; and Examples I and X).

Kardys is deficient in that it does not teach the inclusion of either a C₁ to C₆ alkyl lactate or a stabilizer in the vitamin composition. Kardys also does not explicitly describe a C₂ to C₆ mono-hydroxy alcohol as a necessary component of the composition.

Perricone *et al.* teaches that alkyl lactates and propylene glycol can be used as solvent systems for stabilizing and solubilizing fatty acid esters of ascorbic acid (See Column 3, Lines 25-62 and Column 4, Lines 48-63). Propylene glycol has been described in the application as an example of a stabilizer.

Josse teaches a stable vitamin composition suitable for injection which comprises vitamin A propionate, a vitamin D component (which encompasses vitamin D₃), a vitamin E component,

Art Unit: 1615

a non-ionic emulsifier, a solubilizing agent, and isopropanol (See Column 1, Line 12 to Column 2, Line 5). Both the non-ionic emulsifier and solubilizing agent fall under the category of what the applicant describes as non-ionic surfactants. In addition, isopropanol, which belongs to the category of a C₂ to C₆ mono-hydroxy alcohol as stated by applicant, is seen as a necessary component of the composition taught by Josse.

Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to use the teachings of Kardys in view of Perricone *et al.* and Josse to formulate a liquid vitamin composition as described by the applicant comprising vitamins A, D₃, and E. It also would have been obvious to formulate this composition to be stable and easily dispersed in water by adding an alkyl lactate, a mono-hydroxy alcohol, one or more veterinarian acceptable emulsifiers and non-ionic surfactants, and oil; additionally this composition may also comprise a stabilizer. With regard to the ratio of the alkyl lactate to the mono-hydroxy alcohol, the examiner sees no criticality in the selection of ranges that would be readily determined through routine experimentation to achieve the effectiveness of the vitamin composition. The examiner also does not see any criticality in either the selection of ranges of viscosity of the composition, nor the rate of dispersion of the composition for the same reason stated above.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


THURMAN K. PAGE
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